REMARKS

Claims 1-48 are pending in the application. Applicants respectfully request reconsideration of claims 1-48 in light of the following remarks.

Pages 8-9 of the Action respond to the applicants' previous remarks. The Examiner posits that the combination of Joao and Soll discloses a system for guiding a user along a treatment pathway relating to a previously diagnosed medical condition requiring a medical event. The Examiner points to Paragraph 97 of Soll as disclosing the collection of informed consent of patients for surgery. The Examiner correctly identifies surgery as a medical event that follows a diagnosis, however, the Examiner incorrectly cites the Soll reference as disclosing a treatment pathway for that surgery.

The current claims recite at least one **pre-medical event** set of electronically displayable files containing heath information for **preparing and educating the patient for the medical event**, and at least one **post-medical event** set of electronically displayable files containing health information for **preparing and educating the patient for post-medical event recovery** so as to guide the patient along the treatment pathway. Even if one assumes, *arguendo*, that an informed consent form is a pre-medical event set of electronically displayable files containing heath information for preparing and educating the patient for the medical event for a surgery, neither the Soll nor the Joao references disclose a post-medical event (in the Examiner's example, post-surgery) set of electronically displayable files that prepares and educates the patient for recovery. The post-event files cited in the Examiner's rejection are only exit interviews (Action, Page 4), which are related to the patient's experience with the doctor, not recovery.

Informed consent is not, however, a pre-medical event set of electronically displayable files containing health information for preparing and educating the patient for the medical event. Informed consent is a legal requirement of the patient's state of mind that is imposed upon a provider of medical services such as, in the Examiner's example, a surgery. Informed consent requires that "significant risks be disclosed" about the surgery, "as well as risks which would be of particular importance to that patient" (see "Informed Consent," Wikipedia, attached as Exhibit A). A patient also must be in possession of "his or her reasoning faculties, such as not being mentally retarded or mentally ill and without an impairment of

judgment at the time of consenting" (see "Informed Consent," Wikipedia). Informed consent, and corresponding forms, are thusly indicators of a legal condition allowing the medical service provider to perform a surgery, not a set of tasks that help a patient *prepare* for a medical event, such as surgery, itself.

Turning now to the Action, pages 2-6 of the Action reject claims 1-13, 15-19, 25-39, and 41-46 under 35 U.S.C. §103(a) as being unpatentable over Joao, U.S. Patent Application No. 2001/0032099 ("Joao"), in view of Soll *et al.*, U.S. Patent Application No. 2003/0055679 ("Soll"). Applicants respectfully traverse this rejection.

Independent claims 1, 8, 13, 19, 25, 30, and 39, all recite post-diagnostic methods, systems, and media that guide a patient along a treatment pathway related to a previously diagnosed medical condition requiring a medical event comprising, *inter alia*, pre-medical event and post-medical event tasks that prepare and educate a patient for the medical event and for post-medical event recovery. The Action alleges that Joao and Soll disclose these post-diagnostic treatment pathways leading up to and from a medical event. Applicants respectfully disagree.

Joao discloses a health care system that performs a diagnosis of a patient, prescribes a treatment, and monitors the treatment through the use of medical status measuring devices and diagnosing logic. The Action correctly states that "Joao fails to disclose a system for guiding a patient along a treatment pathway" (Page 4 of the Action). Further, as the system of Joao discloses a diagnosing system, Joao cannot disclose a post-diagnostic system for guiding a patient along a treatment pathway related to a previously diagnosed medical condition, not to mention tasks to be undertaken before and after a medical event required by the previously diagnosed medical condition. Soll discloses a medical treatment system that performs an intake interview with a patient at a health facility (including an informed consent form), aids a doctor in diagnosing the patient, and performs a performance review on the experience. The Action incorrectly cites to Soll at paragraphs 64 and 65 as disclosing the pre-medical event and post-medical event tasks related to preparing and educating a patient for the medical event. In Soll, diagnostic questions are asked of a patient. Educational and "priming" information is provided by the system of Soll to the patient to aid in *answering the diagnostic questions* or

understanding an informed consent form; the information is not directed to preparing for the medical event itself.

In direct contrast to the disclosures of Joao and Soll, the present claims recite a post-diagnostic system, method, and storage media that guides a user along a treatment pathway relating to a previously diagnosed medical condition requiring a medical event through various pre-medical event and post-medical event tasks that prepare and educate a patient for the medical event and for post-medical event recovery. In other words, the medical event is not a diagnosis. The pre-medical event tasks are not related to a diagnostic procedure, as that procedure has already occurred. As neither of the cited references even discuss a treatment pathway in light of a medical event for a previously diagnosed medical condition, not to mention predetermined pre-medical event and post-medical event tasks to educate and prepare a patient for that medical event and subsequent recovery, Joao in view of Soll fails to disclose all of the elements of the present claims. Consequently, Joao in view of Soll can not render unpatentable claims 1, 8, 13, 19, 25, 30, and 39. For at least these reasons, dependent claims 2-7, 9-12, 14-18, 20-4, 26-29, 31-38, and 40-48, also are not rendered unpatentable by Joao in view of Soll.

Pages 6-8 of the Action reject claims 14, 20-24, 40, 47, and 48, under 35 U.S.C. §103(a) as being unpatentable over Joao in view of Soll, further in view of Schoenburg *et al.*, U.S. Patent No. 6,463,417 ("Schoenburg"). Applicants respectfully traverse this rejection.

Claims 14, 20-24, 40, 47, and 48 depend from independent claims 13, 19, and 39, which the applicants believe to be allowable for the reasons mentioned above. Accordingly, claims 14, 20-24, 40, 47, and 48, are not rendered unpatentable as depending from allowable claims.

In view of the foregoing, applicants believe the pending application is in condition for allowance. An early notice to this effect is earnestly solicited. Should there be any questions concerning the foregoing, Examiner Glass is invited to contact the undersigned at the telephone number listed below.

No additional fees are believed to be required for entry and consideration of this response. Nevertheless, in the event that the U.S. Patent and Trademark Office requires any additional fee to enter this response or to maintain the instant application pending, please charge such a fee to the undersigned's Deposit Account No. 50-4494.

Dated: March 27, 2008

Respectfully submitted,

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Exhibit A

Informed consent

From Wikipedia, the free encyclopedia

Informed consent is a legal condition whereby a person can be said to have given consent based upon an appreciation and understanding of the facts and implications of an action. The individual needs to be in possession of relevant facts and also of his or her reasoning faculties, such as not being mentally retarded or mentally ill and without an impairment of judgment at the time of consenting. Such impairments might include illness, intoxication, insufficient sleep, and other health problems.

Some acts cannot legally take place because of a lack of informed consent. In cases where an individual is considered unable to give informed consent, another person is generally authorized to give consent on their behalf. Examples of this include the parents or legal guardians of a child and caregivers for the mentally ill. In cases where an individual is provided limited facts, serious ethical issues may arise. Examples of this in a clinical trial in medical research are anticipated and prevented by an ethics committee or Institutional Review Board.

Contents

Issues surrounding assessment of consent

Informed consent can be complex to evaluate, because neither expressions of consent, nor expressions of understanding of implications, necessarily mean that full adult consent was in fact given, nor that full comprehension of relevant issues is internally digested. Many times consent

Tort law

Part of the common law series

Intentional torts

Assault · Battery · False imprisonment

Intentional infliction of emotional distress (IIED)

Consent · Necessity · Self defense

Property torts

Trespass · Conversion

Detinue · Replevin · Trover

Dignitary torts

Defamation · Invasion of privacy

Breach of confidence · Abuse of process

Malicious prosecution

Alienation of affections

Economic torts

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Conspiracy · Restraint of trade

Nuisance

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Negligence

Duty of care · Standard of care

Proximate cause · Res ipsa loquitur

Calculus of negligence

Rescue doctrine · Duty to rescue

Specific kinds of negligence

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In employment · Entrustment

Malpractice

Duty to visitors

Trespassers · Licensees · Invitees

Comparative and contributory negligence

Last clear chance · Eggshell skull

Strict liability torts

Product liability · Ultrahazardous activity

is implied within the usual subtleties of human communication, rather than explicitly negotiated verbally or in writing. In some cases consent is legally prevented from ever being possible, even if the person protests they do indeed understand and wish. There are also structured instruments for evaluating capacity to give informed consent, although no ideal instrument presently exists.

There is thus always a degree to which informed consent must be assumed or inferred based upon observation, or knowledge, or legal reliance. This especially is the case in sexual or relational issues. In medical or formal circumstances explicit agreement by means of signature which may normally be relied upon legally, regardless of actual consent, is the norm.

Brief examples of each of the above:

1. A person may verbally agree to something from fear, perceived social pressure, or psychological difficulty in asserting their true feelings. The person requesting the action may honestly be unaware of this and believe the consent is genuine, and rely upon it. *Consent is expressed, but not internally given.*
2. A person may state they understand the implications of some action, as part of their consent, but in fact have failed to appreciate the possible consequences fully and later deny the validity of their consent for this reason. *Understanding needed for informed consent is stated to be present but is in fact (through ignorance) not present.*
3. A person may move from friendship to sexual contact on the basis of body language and apparent receptivity, but very few people on a date that results in sexual contact have explicitly asked the other if their consent is informed, if they do in fact fully understand what is implied, and all potential conditions or results. *Informed consent is implied (or assumed unless disproved) but not stated explicitly.*
4. A person below the age of consent may agree to sex, knowing all the consequences, but their consent is deemed invalid as they are deemed to be a child unaware of the issues and thus incapable of being informed consent. *Individual is barred from legally giving informed consent, despite what they may feel (1)*
5. In some countries (notably the United Kingdom), individuals may not consent to injuries inflicted upon them, and so a person practicing sadism and masochism upon a consenting partner may be deemed to have caused actual bodily harm without consent, actual consent notwithstanding. *Individual is barred from legally giving informed consent, despite what they may feel (2).* See also Spanner case and 'consensual non-consensuality'.
6. A person signing a legal release form for a medical procedure, and later feels they did not really consent. Unless they can show actual misinformation, the release is usually persuasive or conclusive in law, in that the clinician may rely legally upon it for consent. *In formal circumstances, a written consent will usually legally override later denial of informed consent (unless obtained by misrepresentation)*
7. A person or institution (e.g. a school or childcare professional) exposes a minor to non-age-appropriate material, in any media format, with out the expressed informed consent of the minor's parent or legal guardian. Informed consent in this instance goes to the argument of competency on the part of the minor. An example would be the showing of an R rated movie to a 12 year old by an educational institution without the informed consent of the parent or legal guardian.

Surgery

The doctrine of informed consent relates to professional negligence and establishes a breach of the duty of care owed to the patient (see duty of care, breach of the duty, and causation in English law).

In the United Kingdom and countries such as Malaysia and Singapore, informed consent requires proof as to the standard of care to be expected as a recognised standard of acceptable professional practice (the Bolam Test), that is, what risks would a medical professional usually disclose in the circumstances (see Loss of right in English law). Arguably, this is "sufficient consent" rather than "informed consent."

In the United States, Australia, and Canada, a more patient-centered approach is taken and this approach is usually what is meant by the phrase "informed consent." Informed consent in these jurisdictions requires that significant risks be disclosed, as well as risks which would be of particular importance to that patient. This approach combines an objective (the reasonable patient) and subjective (this particular patient) approach.

The doctrine of informed consent should be contrasted with the general doctrine of medical consent, which applies to assault or battery. The consent standard here is only that the person understands, in general terms, the nature of and purpose of the intended intervention.

As the higher standard of informed consent applies to negligence, not battery, the other elements of negligence must be made out. Significantly, causation must be shown: that had the individual been made aware of the risk they would not have proceeded with the operation (or perhaps with that surgeon).

The informed consent doctrine is generally implemented through good healthcare practice: pre-operation discussions with patients and the use of medical consent forms in hospitals. However, reliance on a signed form should not undermine the basis of the doctrine in giving the patient an opportunity to weigh and respond to the risk. In one British case, a doctor performing routine surgery on a woman noticed that she had cancerous tissue in her womb. He took the initiative to remove the woman's womb; however, as she had not given informed consent for this operation, the doctor was judged by the General Medical Council to have acted negligently. The council stated that the woman should have been informed of her condition, and allowed to make her own decision.

The doctrine of informed consent also has significant implications for medical trials of new medications.

Competency

The ability to give informed consent will be governed by a general requirement of competency. In common law jurisdictions, adults are presumed competent to consent. This presumption can be rebutted, for instance, in circumstances of mental illness or other incompetence. This may be prescribed in legislation or based on a common-law standard of inability to understand the nature of the procedure. In cases of incompetent adults, informed consent--from the patients or from their families--is not required. Rather, the medical practitioner must simply act in the patient's best interests in order to avoid negligence liability.

By contrast, 'minors' (which may be defined differently in different jurisdictions) are generally presumed incompetent to consent. In some jurisdictions (e.g. much of the U.S.), this is a strict standard. In other

jurisdictions (e.g. England, Australia, Canada), this presumption may be rebutted through proof that the minor is 'mature' (the 'Gillick standard'). In cases of incompetent minors, informed consent is usually required from the parent (rather than the 'best interests standard') although a parens patriae order may apply (allowing the court to dispense with parental consent in cases of refusal).

Abortion

In some U.S. States, informed consent laws (sometimes called "Right To Know" laws) require that a woman seeking an elective abortion be given factual information by the abortion provider about her legal rights, alternatives to abortion (such as adoption), available public and private assistance, and medical facts (some of which are disputed - see fetal pain), before the abortion is performed (usually 24 hours in advanee of the abortion). Other countries with such laws (e.g. Germany) require that the information giver not be affiliated with the abortion provider, to avoid giving an economic incentive for handing out faulty information.

Sex

The question of whether informed consent needs to be formally given before sexual intercourse or other sexual activity, and whether this consent can (and must be able to) be withdrawn at any time during the act, is an issue which is currently being discussed in the United States in regard to rape and sexual assault legislation. For example, people who perform sexual acts on sleeping people are not given consent unless the initiator have given prior informed consent to the act within a reasonable recency, and are assumed to be consenting during the act and to not prosecute for it when waking up. This is also an issue in rape fantasy enaction which is often discussed by a "ravishment community" of participants (a subset of the BDSM community) who advocate extensive prior negotiation and planning. The issue of prior informed consent may also come up if the legality behind consensual necrophilia is ever further explored.

While children may be able to give consent, a more complex question applies in terms of informed consent: whether children are developmentally and otherwise able to give informed consent, in particular to an adult, bearing in mind power relationships, maturity, experience and mental development. For this and othcr reasons most states have an age of consent under which a child is deemed unable to give consent. As evaluation of maturity, mental maturity, child development, child communication, and child intelligence are further explored, this may be based on psychological and medical evaluation of status for sexual activity instead of chronological age.

Animals are not usually considered able to give informed consent in a legal sense (although advocates and some ethologists argue they have the capability to agree and strongly solicit such activity), and partly for this reason, but more usually due to concerns for morality and abuse, bestiality is illegal in many jurisdictions. As animal communication methods and evaluation of animal intelligence and animal sexuality changes, this may also change.

No-victim laws

It may not be legally possible to give consent to certain activities in certain jurisdictions; see the Operation Spanner case for an example of this in the UK which involved sadomasochistic activities such as branding. There are currently several legal challenges underway to address these issues of legality in

several nations.

(*See also:* "Victimless crime")

Research

Informed consent is also important in social research. For example in survey research, people need to give informed consent before they participate in the survey. In medical research the Nuremberg Code has set a base standard since 1947, and most research proposals are reviewed by ethics committees in the 21st century.

See also

- World Medical Association
- Human experimentation
- International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
- Declaration of Geneva
- Declaration of Helsinki
- Belmont Report
- Safe, sane and consensual
- Consent (BDSM)
- Consent (criminal)
- Consensual crime
- Parental consent
- Minors and abortion
- MKULTRA
- Illegal Medical Experiments and the United States Government
- Informed consent on Wipipedia, the BDSM encyclopedia
- Informed refusal

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- Informed Consent: Legal Theory and Clinical Practice by Jessica W. Berg, Paul S. Appelbaum, Lisa S. Parker, and Charles W. Lidz, Oxford University Press, 2001

External links

- Informed Consent (http://depts.washington.edu/bioethx/topics/consent.html) (University of Washington School of Medicine)
- A Guide to Understanding Informed Consent (http://www.cancer.gov/clinicaltrials/conducting/informed-consent-guide/page1) (National Cancer Institute, USA)
- Consentimento Informado (http://www.bioetica.ufrgs.br/consinf.htm) (Bioética e Ética na Ciência/Brasil)

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